JUL 2 4 2002

Aerotel Medical Systems (1998) Ltd.
Special 510(k) Submission
Heartline Receiving Station

510(k) Summary

(1) Submitter Information

Name: Aerotel Medical Systems (1998) Ltd.

Address:

5 Hazoref Street
58858 Holon
Israel

Telephone Number: 972-3-559-6111

Contact Person:
Dr. George Myers (Official Correspondent)
Medsys Inc.
377 Route 17 S
Hasbrouck Heights, NJ 07604
Telephone 201-727-1703
Fax 201-727-1708

Date Prepared: June 19, 2002

(2) Name of Device

Trade Name: Heartline Receiving Station
Common Name: Electrocardiographic Telephone Event Receiver/Transmitter
Classification name: Transmitters and Receivers, Electrocardiograph, Telephone
74 KGJ.

(3) Equivalent legally-marketed devices.

Aerotel Heartline receiving Console, K930314

(4) Description

The Heartline is an ECG monitoring device intended to receive ECG signals

over standard telephone lines from patient operated transmitters. When decoded, received signals are recorded and patient data can be displayed on a PC monitor for physicians analysis and comment. The HRS is basically a software system, and operates on commercial personal computers. The device is compatible with all Aerotel monitors, all of which have been cleared by the FDA.

(5) Intended Use

The Heartline Receiving Station is indicated for use when patients transmit electrocardiographic signals from remote cardiac ECG event recorders to a central station.

(6) Performance Data

(a) Non-clinical tests

The programs for the Heartline Receiving Station have been thoroughly verified and validated. The recommended computers meet international standards for electrical safety and electronic emissions.

The entire system has been validated.

(b) Clinical tests

Not required.

(c) Conclusions

The Heartline Receiving Station is equivalent in safety and efficacy to the legally-marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 4 2002

Aerotel Medical Systems
c/o George H. Myers, Sc.D.
President
Medsys Inc.
377 Route 17 South
Hasbrouck Heights, NJ 07604

Re: K022073
Trade Name: Heartline Receiving Station
Regulation Name: Telephone Electrocardiograph Transmitter and Receiver
Regulation Number: 21 CFR 870.2920
Regulatory Class: Class II (two)
Product Code: DXH
Dated: June 24, 2002
Received: June 26, 2002

Dear Dr. Myers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Page 1 of 1

510(k) Number (if known):

Indications for Use Form

Device Name: Heartline Receiving Station

Indications for Use:

"The Heartline is an ECG monitoring device intended to receive ECG signals over standard telephone lines from patient operated transmitters when decoded, received signals are recorded and patient data can be displayed on a PC monitor for physicians analysis and comment. "

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Cardiovascular
and Respiratory Devices
510(k) Number K022073